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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,337	05/09/2006	Seong Hwan Cho	1751-0400	8934
6449 7590 08/12/2009 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER				
ROYDS, LESLIE A				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
08/12/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

### Office Action Summary

**Application No.**

10/574,337

**Applicant(s)**

CHO ET AL.

**Examiner**

LESLIE A. ROYDS

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

**Claims 1-16 are presented for examination.**

Applicant's Amendment filed March 25, 2009 has been received and entered into the present application.

Claims 1-16 remain pending and under examination.

Applicant's arguments, filed March 25, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinoda et al. (U.S. Patent Application Publication No. 2003/0147948; 2003), already of record, for the reasons of record set forth at p.3-4 of the previous Office Action dated December 31, 2008, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that Shinoda et al. discloses a sustained-release formulation that comprises sustained-release fine particles that include several polymers, but fails to disclose a sustained-release formulation that comprises all of the elements set forth in instant claim 1. Applicant alleges that Shinoda et al. discloses a particle core coated with a layer comprising active ingredient (i.e., tamsulosin) and a polymer, such as hydroxypropylmethylcellulose, which is then coated

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with ethylcellulose and hydroxypropylmethylcellulose and coated with ethylcellulose. Applicant alleges there is no disclosure of layering an active-ingredient containing film coating layer on an enteric film layer coated on a sustained-release core.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant appears to be restricting his consideration of Shinoda et al. to Example 1 of the disclosure, which teaches a tamsulosin hydrochloride formulation and hydroxypropylmethylcellulose, which is then coated with ethylcellulose. This argument is unimpressive, since the teachings of Shinoda et al. are clearly more extensive than only those teachings contained within Example 1 of the disclosure. Specifically, Applicant is directed to the cited portions of Shinoda et al. as noted in the previous Office Action and is further directed to para.[0074] of Shinoda et al. for further clarification of the arrangement of the active ingredient and polymeric materials of the disclosed sustained-release formulations.

In particular, note that Shinoda et al. very specifically teaches that the sustained-release particles are formulated by layering the drug onto a core particle (i.e., commercial crystalline cellulose particles, crystalline lactose, granular sugar, sodium chloride, silicon dioxide, etc.) using a binder such as hydroxypropylmethylcellulose, wherein the particle is then further coated with a polymer substance, such as, *inter alia*, an enterosoluble polymer substance (defined at para.[0055] as including enterosoluble acrylic acid copolymers, such as methacrylic acid-ethylacrylate copolymer). Shinoda et al. further discloses that a polymer substance with drug may be layered onto the particles to make a sustained release particle, wherein Shinoda et al. teaches that substances such as, *inter alia*, polyvinyl alcohol may be mixed with the polymer components (which meets Applicant's part (c) of the claimed formulation, since Applicant has elected polyvinyl alcohol as the hydrophilic polymer for film coating) and the particles may then be given enterosoluble function by coating with an enterosoluble polymer base as necessary (of which Shinoda et al. explicitly teaches methacrylic acid-ethylacrylate copolymer at para.[0055] as an enterosoluble polymer). Please see, e.g., para.[0074] of Shinoda et al. This is a clear teaching of not only

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the same elements as those instantly claimed in at least claim 1, but also a clear teaching of the same conformation of elements as instantly claimed (i.e., of the same structural arrangement as that recited in instant claim 1), absent factual evidence to the contrary and/or any substantive remarks directed to what specific elements of the instantly claimed invention Applicant asserts are lacking from the teachings of Shinoda et al.

For these reasons *supra*, and those previously made of record at p.3-4 of the Office Action dated December 31, 2008, rejection of claims 1-16 is proper.

### ***Conclusion***

Rejection of claims 1-16 is proper.

No claims of the present application are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE A. ROYDS whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/  
Patent Examiner, Art Unit 1614

August 6, 2009

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614